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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,551	01/31/2002	Michael A. Apicella	875.045US1	2735

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/066,551	APICELLA ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 7, 15, 21, 23-25 and 60-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,7 and 65-68* is/are allowed.

6)☒ Claim(s) *15,21 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Amendment

1. The amendment filed on 12/27/05 is acknowledged.

Status of Claims

2. Claim 15 has been amended.

New claims 60-68 have been added.

Claims 2-6, 8-14, 16-20, 22 and 26-59 are cancelled.

Claims 1, 7, 15, 21, 23-25 and 60-68 are under examination.

Claim rejection 101 withdrawn

3. In view of amendment to claim, the rejection under 35 U.S.C. 101 is withdrawn.

Claim Rejections - 35 USC 102 withdrawn

4. In view of amendment to the claim and arguments of record, the rejection under 35 U.S.C. 102(b) as being anticipated by Fraser et al 1999 is withdrawn.

Claim rejection 35 USC 112, first paragraph maintained

5. The enablement rejection of claims 15, 21, 23-25 (vaccine composition) and newly added claims 60-64 under 35 U.S.C. 112, first paragraph is maintained as set forth in the previous office action.

Instant claims are evaluated for enablement using the Wands analysis. Many of the factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the disclosed invention is drawn to a vaccine composition for the treatment or cure of a disease or prevention of an infection caused by *Neisseria gonorrhea.* The state of the art indicates (Barritt et al, Infect and Immu1987, 55:2026-2031) the outermembrane protein antigens of *N.gonorrhoeae* are highly variable. The family of proteins that show variation are the surface exposed proteins II (P II) and Opa proteins. These variations enable the bacterium to evade the host immune response and adapt to differing host environment.

Both pilin and Opa proteins undergo considerable variation in vivo as inoculation of strains FA1090 and strain MS11 with Opa negative population of gonococci resulted in reisolation of mostly Opa positive gononcocci indicating that there is a strong selection for expressing Opa proteins in vivo (see IDS,8/9/04 Cohen and Canon, JID 1999, 179(suppl) S375 –379). However, experimental studies are only pursued in men, since the complications in women would outweigh any potential benefits. The protein P55 or protein comprising the amino acid sequence SEQ.ID.NO: 4 (strains, MS11 and strain 1291, encoding secretion system) would directly inhibit the infectivity at least in vitro studies have not been established. It is unpredictable whether the claimed composition induces an immune response sufficient to inhibit gonorrhea disease caused by various clinical strains of *Neisseria gonorrhea* because the prior art discloses that the human pathogen *N.gonorrhoeae* is endowed with a wide range of mechanisms that facilitate immune avoidance including antigenic shift in the expression of surface antigens. Because of this antigenic shift the development an effective vaccine has resulted in frustrated attempts (see introduction of Paz et al 1995, Microbiology 141, 913-920, reference cited in Form 892, 7/20/03). The specification has not disclosed a link or nexus between the generation of protective immunity and the claimed polypeptide. Further, it is not routine in the art to use the claimed compositions for this purpose. Accordingly, there is no objective basis upon which the skilled artisan would reasonably be able to determine or predict an amount of the claimed vaccine effective for its intended use.

Applicants arguments filed on 11/28/05 have been fully considered but they are not deemed to be persuasive.

Applicant states that the examiner has initial burden of setting forth a reasonable explanation as to why (he/she) believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification and cites several case laws of record. The Examiner bears the burden of providing evidence or technical reasoning to substantiate her doubts that the specification is not enabling with respect to the scope of a claim sought to be patented.

The examiner established the enablement rejection based on the wands analysis as set forth in the above rejection. Since there are no working examples, the examiner considered the guidance provided by the instant specification and the state of the art of record. The art teaches antigenic shift is the main problem in the development an effective vaccine. The specification on pages 68- 78 indicates antibodies to CR3, CD18 inhibit the binding of *N.gonorrhoeae* to cervical epithelial cells. Based on this analysis, the examiner established the rejection and indicated

that it is necessary to establish a nexus between protective immunity and the claimed polypeptide since vaccine composition is for the prevention of an infection caused by *Neisseria gonorrhea* strains. The art teaches *Neisseria gonorrhea* undergoes antigenic variation at a higher rate in immune evasion and this variation in a strain changes ability to bind to specific antibodies and this avoiding immune recognition.

Applicant states that the specification pages 54-56 teach different strains of N.gonorrhoeae in the art accepted *ex vivo* model.

The examiner looked at the pages 54-56 and found that only wild type 1291 has been used. Therefore, applicant's argument does not support the issue of antigenic shift, as raised by the examiner since clinical strains of *Neisseria gonorrhea (in vivo isolates)* undergo antigenic shift/antibiotic-resistant etc and would not recognize the antibodies to the claimed polypeptide.

The examiner is well aware of the difficulties in establishing an *in vivo* model for screening vaccines and ex *vivo* model is the only choice left for those skill in the art for screening antibodies or antibiotics etc. However, there is no evidence of record that p55 in clinical strains of Neisseria *gonorrhea* is not prone to antigenic shift or do not develop resistance to antibiotics such that it can be used as a vaccine for *Neisseria gonorrhea.* The Declaration of record indicates only antibodies to p55 are able to block wild type 1291 Neisseria. Therefore, the enablement rejection for vaccine is maintained.

Remarks

6. Claims 1, 7 and 65-68 are allowed.

Claims 15, 21 and 23-25 stand rejected.

Conclusion

7. **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

8. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature

or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600